John Beigel, Lori Dodd, Seema Nayak, Kay Tomashek, and Walla Dempsey

Behind the Mask

April 5, 2022

Barr: Good afternoon. Today is April 5, 2022. My name is Gabrielle Barr, and I'm the Archivist at the Office of NIH History and Stetten Museum. Today I have the pleasure of speaking with some of the many people who were instrumental in putting together the NIH ACTT [Adaptive COVID-19 Treatment] Trials. They include Dr. John Beigel, who is the Associate Director for Clinical Research in the Division of Microbiology and Infectious Diseases at the National Institute of Allergy and Infectious Diseases (NIAID); Dr. Lori Dodd, who's a Mathematical Statistician in the Biostatistics Research Branch, also at NIAID; Dr. Seema Nayak, who is the Director of the Office of Clinical Research Resources; Dr. Kay Tomashek, the Medical Officer in the Office of Clinical Research Resources; and Dr. Walla Dempsey, who is a Clinical Research Program Officer in the Virology Branch at NIAID. Thank you all for being with me today. To begin, when did you all begin conceptualizing studies that looked at remdesivir as a treatment for COVID-19, and what was it like getting this very large, multi-part, international study underway?

Beigel: I'll start, and then we can hand it off. The discussion of this trial actually went back to January 2020, and at that time, there were no cases of COVID in the U.S. There were small outbreaks occurring in China, and there were some infections occurring on cruise lines. There was a discussion internal to the government and with colleagues from the CDC [Centers for Disease Control and Prevention] that discussed how we would treat people that were infected on the cruise line. We had no idea whether we would ever see cases in the U.S. or not, but we thought it was important to start a study in anticipation of treating people that were on cruises or otherwise got infected. We anticipated just a few cases, and we really struggled to even know if we would enroll a study or not. We started the study a few weeks later in February of 2020.

Barr: Was that based on seeing the results of remdesivir with the Diamond Princess patients?

Beigel: It was based on the results of remdesivir in the pre-clinical studies, which we thought would be effective against coronavirus. It had been tested in Ebola and a few other trials, so we had some idea about the safety of remdesivir. We thought it should be effective, but we didn't know for sure.

Nayak: It very quickly went on from there in putting the trial together. I would say one way to describe those first few weeks would be “intense”—all hands on deck. It was very fast-paced and brought a lot of internal and external stakeholders together.

Barr: Can you talk a little bit more about some of the stakeholders you reached out to, and how you communicated with them? Did you all have regular meetings with them?

Beigel: I'll start some of that discussion. We had several internal stakeholders—internal to the U.S. government. We had regular conversations with colleagues from the CDC, from BARDA [Biomedical Advanced Research and Development Authority], and from the FDA [U.S. Food and Drug Administration], and they were all interested and supportive, and facilitated getting a trial started. We also had multiple external stakeholders. We tapped into networks that we've worked with before, as well as colleagues that we've worked with on other trials, and colleagues that reached out to us because they heard we were doing a study. We were able to bring in all these internal stakeholders, external partners, and teamed up with Gilead in order to get the study started quickly.

Tomashek: What was unique is we had some partners that had never worked with NIH and some that had never done an inpatient clinical trial. For example, after several passengers on the Princess cruise became ill with Covid-19, our first enrollment in ACTT-1 was in Nebraska with sick passengers who were in federal quarantine. Within a week, I went to Evergreen in Washington state, because they had just had 24 Covid-19 deaths at a nursing home associated with individuals that had returned from travel to China. The staff at the hospital in Evergreen had never worked with us, but again, it was an early hot spot so we worked with their staff and brought them on board as one of ACTT's clinical trial sites. In the early days (February-March of 2020), we focused on cities and hospitals that had Covid-19 cases. You go to where the cases are. That's where we tried to get interest in terms of conducting clinical trials—in those hospitals that had cases.

Barr: Were you guys in charge of helping with the recruitment of participants, or was that mostly on the external sites of your partners?

Tomashek: Study recruitment is done at the clinical site, at the hospital. They're the individuals who are seeing the patients with Covid-19. We trained them on the study protocol, so they knew the necessary eligibility criteria and could identify patients who qualified for enrollment. It's the primary investigator and his or her staff who recruit and enroll patients into the study, not us. We help by answering phone calls from the PIs [principal investigators] and from study staff including nursing coordinators who have questions about the study protocol including whether an individual is eligible for study enrollment.

Barr: Can you all explain your methodology for the first ACTT study, such as how many participants you recruited, some of your eligibility criteria, and the types of equipment that were used in your metrics for evaluating the results?

Tomashek: John, do you want me to give kind of a high-level overview?

Beigel: Sure, that would be great.

Tomashek: What was nice about ACTT is that it was an adaptive trial, which means that ACTT-1, -2, -3 and -4 were all very similar designs. They were randomized, double-blind, placebo-controlled trials. They were adaptive in that they evaluated different novel therapeutics for adults hospitalized with COVID, but the key design elements were the same. Blood draws were on the same day in all the trials—days 1, 3, 5, 8, and 11 while they were hospitalized. And the follow-up visits were the same as well. The study population were adult individuals that were 18 years old or older that were hospitalized with COVID. In the different ACTTs, we evaluated different

study products with different safety profiles, so we had to adjust the exclusion criteria to make it safe for eligible patients to participate in the trials. The adaptive design allowed us to be very efficient because, essentially, a similar study design was used through all four ACTTs.

Barr: I had two questions about that. I saw that in many of the ACTTs, pregnant and lactating women are always a challenging population, and I saw that you weren't recruiting them, but at times remdesivir could be given under compassionate use. Can you speak more about that? That's my first question. My second question is: Why were those who were experiencing mechanical ventilation not included in the ACTT trial?

Beigel: To talk to the first question, when we started the study, we didn't know whether remdesivir was beneficial or not. The concern was we would expose pregnant women to a drug that may be harmful to their child, and we don't know if it was beneficial. When we showed that the remdesivir actually was beneficial, then that became standard care, and even pregnant women could then receive it. But then, when we went on and we were exposing the pregnant women to another drug—and again, we didn't think we could expose that woman to a drug unless we knew it was beneficial to them. To your second question, the ACTT-1 and -2 studies did allow for inclusion of participants that were on mechanical ventilation. It was ACTT-3 where that was separated, but ACTT-1 and -2 did allow it.

Barr: Okay. Interesting. Were you all surprised by the results of the first ACTT study? How did you feel the administration of remdesivir for SARS-CoV-2 compared with when it was prescribed as a treatment for MERS [Middle East respiratory syndrome] and SARS-1?

Beigel: Lori, do you want to start the discussion?

Dodd: Sure. I will say, I was very shocked because the trial enrolled so quickly. We were just doing our part to keep things moving at the high quality that the ACTT study set, in terms of making sure we had really high-quality data. What happened was there was an interim analysis, which is a statistical method of evaluating whether the current evidence is strong enough to conclude that this is a statistically significant effect. At that interim analysis, which was conducted by a totally independent body, a data safety monitoring board—it's a formal group; they're independent from the study. They evaluated the data. We had no idea, and when I heard the news, I mean, I nearly fainted, because I had no idea that we were close to even crossing what we call a stopping boundary—or basically, that we were so close to showing that there was an effect from remdesivir.

Barr: That's great. What was it like collecting all that data from all those different sites and participants, and analyzing it in such a short amount of time?

Dodd: First of all, it took a massive effort from a lot of very well-trained individuals. We had our own internal NIAID team. We had contractors from Emmes who have a lot of experience. John, you could tell us the numbers of staff. We also had support from Leidos contractors. It was a major effort, and it was exhausting for everybody. I think this was an effort where everybody worked, probably harder than they have ever worked, to make sure that the data were of high quality, and then to make sure the analyses were accurate.

Nayak: Then we also had our sites. We had our investigators, study coordinators, nurses, pharmacists, and all of these people that are just so instrumental in collecting this data. It really was, for them as well, an all-hands-on deck situation, where people were getting enrolled very quickly, and you have to be really on top of not only the safety parameters, but also the data that's being collected. And they were.

Barr: That's great. We're going to move on to the second ACTT study. Why was the drug baricitinib, in conjunction with remdesivir, thought to be a good therapy for those with severe COVID?

Beigel: There was early data to suggest that there were high levels of cytokines, which are proteins that help the immune system function, so there were high levels of these pro-inflammatory proteins. And there was some small set of data to suggest that using a drug like baricitinib could help bring those levels down. Now we didn't know if that was a good thing—to bring those levels down. Certainly, there are examples and other diseases where if you give drugs to counteract the immune system, you actually make things worse, because an immune response is important. We didn't know if it was good to modify the immune response in that way. But given how high these markers of inflammation were, and that the people that did the worst tended to have the highest levels, it seemed like an appropriate path to study,

Tomashek: Even though there were potential risks, like Dr. Beigel was saying, we were monitoring participant safety in these clinical trials. Each ACTT study enrolled about 1,000 participants, so they were mid-sized studies, a good size to be able to monitor and detect a safety signal. Having learned from ACTT-1, I think we were reassured we could study baricitinib safely.

Barr: Can you speak a little bit about the primary and secondary outcomes of this study? Since the conclusion of the study, has that combination become standard of care for critically ill COVID patients?

Beigel: Lori, do you want to talk about outcomes?

Dodd: Yeah, I can talk about outcomes generally. I'll just make a comment that when we started conceiving of the study in January 2020, we knew very little about what is now called COVID-19. At the time, it wasn't even called COVID-19, so we had to really struggle to define the appropriate measure for the study outcome. We needed a way to measure whether an investigational agent improved patient outcomes. In clinical trials we look for endpoints that measure the way a patient feels, functions or survives. We first looked to endpoints for flu which led to the use of the ordinal scale on a specific day, which was an initial endpoint that was used. As we learned more about the course of COVID illness as reports came from China, we learned that the disease lasted a lot longer than was initially thought and measurement at a specific day may miss important benefits of an effective drug The end point was changed to time to recovery over 28-days, which is basically the same as time to hospital discharge. Time to recovery was utilized for the first three ACTTs and was really meant to indicate an improvement in the speed of a patient's recovery. I'll stop and see if anybody wants to add to that.

Beigel: Did it become standard care? At the same time that we were doing this study, there was a group in the U.K. that was doing a study on corticosteroids, specifically dexamethasone, which was approaching the same problem—the idea of how you bring that immune response down. And that study actually announced their

results a few weeks before—actually probably a few months before—we announced our results. A few weeks before our study was done, they announced their results, and the dexamethasone quickly became the standard of care. Baricitinib is used, but it's used much less frequently, because dexamethasone is cheaper, it is available worldwide, and they had the data first.

Barr: Okay, has any of that care changed at all as the disease has progressed? COVID-19 now looks very different than it did even just a couple of months ago.

Beigel: Yeah. I mean, it certainly is less severe now. Part of that is that it is in a population that has some immunity. Most people have some immunity now, either by a vaccine or by prior infections. The Omicron variant, even on top of that, seems to be a milder variant, so there is not the same degree of robust inflammatory response that we saw in the past. There are certainly discussions of how that impacts care and less use of corticosteroids, but I still think that corticosteroids are probably the mainstay, and baricitinib is a backup.

Barr: Okay, we'll move on to ACTT-3. The ACTT-3 study looked at how interferon beta one, which tends to be [used for] with those with multiple sclerosis, and remdesivir, performed in helping those with severe COVID in comparison with just administering remdesivir. Can you speak a little bit about what your findings were, how those patients fared in comparison to those that just received the baricitinib and remdesivir combination, and did you have any patient who had auto antibodies who affected the efficacy of the treatment?

Beigel: All good questions. I'll start just to give you a setup of why we've studied this.

Barr: That would be really helpful.

Beigel: In the summer of 2020, there was a fair amount of discussion that, early in COVID, there might even be a low immune response, and that people weren't generating enough immune response early in the disease. And there were reports of people having antibodies to interferon and maybe getting the disease more often. It was a fair amount of data coming together at that time to suggest that maybe one way to improve the immune response is to give something like interferon, which stimulates the immune response, and especially to do it early. For that reason, we excluded those that were already on mechanical ventilation, to your point that you raised before. When they are on mechanical ventilation, there's such an inflammatory cascade going on, that giving them something like interferon to push even further was probably not going to be beneficial. We thought giving it early in the disease would actually, or at least potentially could, improve outcomes. Kay, do you want to talk about what it showed?

Tomashek: ACTT-3 was essentially a negative study, which means there was no difference between the individuals who received interferon and remdesivir versus those who received remdesivir alone. And in fact, we found that individuals that had higher oxygen requirement and needed high flow oxygen at baseline (ordinal scale 6), did not do very well. They had more safety signals than those that were just given remdesivir alone. In the end, use of interferon and remdesivir was not superior to remdesivir alone.

Beigel: Our thought is that maybe once they're in the hospital, that that inflammatory cascade has already started. There are people working on interferon still, looking earlier in the disease. And there was actually something just a few weeks ago about a type of interferon in outpatient early disease that maybe would be beneficial. It comes back to that you can't treat this entire disease as a homogenous group. They're very different, and treatments that work early in the disease may not work late in the disease, and vice versa.

Tomashek: We categorized the individuals who volunteered in ACTT by ordinal scale at the time of enrollment. The ordinal scale was a way to measure our primary outcome of recovery and consisted of 8 levels of intervention needed in terms of whether oxygen supplementation was needed or not, or whether they needed to be intubated. Guidelines, like the NIH Covid-19 Treatment Guidelines, are also divided by ordinal scale.

Barr: Well, do you guys have any plans for conducting subsequent research based on your first three ACTT studies? Are you looking into any other drugs for COVID-19?

Beigel: We did conduct an ACTT-4, and that is completed but not yet published. We anticipate it will be published hopefully in the next month or two. It's been a long time with the publisher, but we anticipate that will come out.

Barr: What did your ACTT-4 focus on?

Beigel: Walla, do you want to talk about ACTT-4?

Dempsey: ACTT-4 looked at the combination of baricitinib and dexamethasone to see if one or both were more effective at impacting the immune inflammatory conditions that were associated with COVID-19.

Beigel: It comes back to what we said about ACTT-2, right? I mean, ACTT-2 worked, dexamethasone worked, but we didn't know which one was better, or if they were similar. That's what that study was meant to evaluate.

Barr: Well, that's really great. Do you have any other trials in the works?

Beigel: We don't right now. We've got other vaccine studies. I need to get back to you about talking to the vaccine team because I think that's a whole separate discussion. With [COVID-19] disease getting less severe, as we've already discussed, and with most people having more of an immunologic background, we think that the most critical need is actually prevention rather than treatment. We are not, right now, planning any additional treatment studies, but we are doing additional vaccine studies.

Barr: Can you speak a little bit about the ACTIV-5 Big Effect Trial for the treatment of COVID-19, which is a proof-of-concept study, and what therapeutics were tested, and which ones were planned to be tested in the second phase of the trial?

Beigel: Seema, do you want to tackle that?

Nayak: Sure. We tested three drugs in the ACTIV-5 study. The first was risankizumab. The second was lenzilumab, and the third was an oral drug, danicopan. Again, as John said, it was a proof of concept, so we had a smaller number of participants, and that trial just closed to enrollment. We're still in safety follow-up for two of the arms, and we're hoping that we'll have some data this summer.

Barr: That'll be exciting. Can you all speak a little bit about some of the challenges that you have experienced in working on all the trials since the beginning of the pandemic, and some things that maybe you've learned overall?

Beigel: I think everybody's got stories here. Walla?

Dempsey: Some of the major challenges, besides just the pandemic and developing a protocol so rapidly, had to do with operationalizing the trial. Shortages occurred because things were being shut down during the pandemic. Many of our sites couldn't easily accept packages or study supplies or drugs that we needed to ship to them because their facilities were closed. Staffing at all of these facilities was challenging in that, while the primary clinical people may be there, the support staff, the support laboratories, the phlebotomist, and everything else was limited. The availability of the actual initial supplies of drugs for the remdesivir trial was a huge challenge. The company could not manufacture the product fast enough for their trials and ours, or the demand that was increasing worldwide. There's too many to actually describe all of them.

Beigel: Kay, you've got stories too.

Tomashek: Well, to add to Walla, I think that because of the pandemic and the staffing shortages, there was always a need for technical assistance. We were being called a lot. We had a call line that was set up for our clinical trial sites. On any given ACTT, we had about 65 sites that were enrolling. The first ACTT was in 10 different countries, so they're enrolling all over, day and night. We had a call schedule set up, and we would take calls and answer questions from the site about the product, enrollment, protocol deviations—anything operational.

Barr: You had somebody available to field phone calls 24/7?

Tomashek: It wasn't 24/7, it was 7:00 in the morning till about 12:00 at night. So almost 24/7.

Beigel: But just to clarify that person that mainly took the calls was Kay. They had Kay's personal cell phone number.

Tomashek: No, they had other people's phone number too. It wasn't just me. But I think that was challenging. It was good in that as we progressed, they got more used to the study procedures and became more proficient, but there were always questions. The other thing that I think presented unique challenges was the fact that our study participants were hospitalized, and they were in quarantine. They were in isolation and away from their families. It was very difficult to get informed consent from individuals who are in isolation in these hospitals. We

had to work through those issues and develop processes to safely inform individuals about the study and then get informed consent. Those two issues, in addition to what Walla said, were huge issues for our team.

Barr: What were some of your solutions to that?

Tomashek: Some groups did informed consent through a glass window, with the patient, in isolation, reading the consent form on the other side of the glass. Others had someone go into isolation and describe the study to the patient. After the consent form was signed, they would put the signed sheet in a package. This was early in the outbreak when we thought the droplets were so contagious. Over time, it evolved, and FDA came out with guidance for Covid clinical trials, because it was very difficult with shortages of personal protective equipment and staff shortages. I think the most difficult thing was when you would have an individual that needed someone in their family to help them consent for a study, like a legally authorized representative. That was a barrier for elderly people to participate because the legally authorized representative wasn't allowed into the hospital during those early days. All those issues came up during this pandemic, because of the quarantine and the strict isolation of people who had the disease.

Nayak: Staff would get pulled just to be doing clinical care for patients, so it was harder to enroll in a trial sometimes. We had supply issues with the tubes that you do blood draws with. Things like that, that were unique to the pandemic. Just putting together such a large trial and so many sites from different countries and different networks—there was a learning curve with that, but overall, it was very successful. Everyone came together to get it done, and in a timeline that was amazing,

Dempsey: Don't forget that during all of this, the personal protective equipment for the sites was in very limited supply, and so getting in to see a patient multiple times a day to obtain the data or the labs that you needed, in many cases, wasn't possible. We had to streamline as much as we could.

Barr: That's really hard. Can each of you introduce your roles with this initiative, particularly the ACTT trials?

Dodd: Before we go there, would you mind if I added a couple of challenges? I had a couple of things. One, I think communication was a major challenge on many levels, including that there was a lot of pressure to communicate results very quickly. We heard the term “science by press release.” That was the first time I'd ever heard that term used, and as a study team that's focused on quality, we really wanted to make sure that when we released any results, we were sure of the quality of them. That had to be counterbalanced against this massive pressure—especially with ACTT-1 because there was no treatment at that time that had been proven to be efficacious—to get something out there for the public. Balancing that, I thought, was really, really challenging. As time went on, there were more trials running, and you never knew when a new result was going to come out. The uncertainty of not knowing if another major trial was going to suddenly come out with a result that meant that what you were doing somehow needed to stop or be altered in a significant way, was another challenge. I remember going to bed at night thinking, “Okay, what am I going to do if this thing happens in the next day?” and trying to figure out how we would have to adapt the study to anything that might come our way. We had to stay aware of what was happening to anticipate and plan. That was really challenging for me.

Barr: I'm sure.

Tomashek: In the beginning, there wasn't as much competition for trial participants when we started the trial in February of 2020. We enrolled our first participant on the 21st of February. But by the time we got to May, there was a lot more competition with other trials in terms of enrollment. It was harder and harder to enroll, especially as we enrolled ACTT-3 and -4. Like Lori said, it was really difficult. I remember when the [United Kingdom's] Recovery Trial came out with their results on dexamethasone, and we had 10 days left of ACTT-2. I thought, "Oh my goodness, how is this going to affect our results now that dexamethasone may become the standard of care?" It was just like every day was another adventure with new findings that may be bad news in terms of how it may impact the results of your study, but potentially good news for all the patients out there.

Barr: Yeah, before we get to the roles—and Lori, you mentioned it briefly—how did you all deal with all the formal and informal press about the trials? I mean, never has it been more visible to all kinds of people.

Beigel: I mean, there is a lot of interest, as you said, in the results. There's a whole process at NIAID and within the NIH of how those results get conveyed. Many of them involved conveying through the formal mechanisms and having [NIAID Director] Dr. [Anthony] Fauci convey some results. We were largely focused on getting the trials done while other groups managed the press.

Dempsey: We did have to notify the status of the trials daily to central NIAID, central NIH, and HHS [U.S. Department of Health and Human Services].

Barr: That's interesting. Can you speak a little bit about your roles and what expertise you added to the trials?

Beigel: Sure. I would equate my role to ringmaster—trying to let everybody do what they focus on, and empower them to run with certain things, while keeping it all in some sort of a coherent process. That was my role—to try to bring all these pieces—internal, external, all the contracts—together.

Tomashek: My role was Medical Officer. As Medical Officer, I worked with John and everyone you see here, as well as the whole study team, to write study protocols—basically revise study protocols as needed—and also to develop study materials, like the informed consent and method of procedures and instructions of how to conduct the study.

Barr: Did you model those on previous studies, especially the first one, or did you come up with a whole new study design just for COVID?

Tomashek: No, it was a standard study protocol. Like I mentioned earlier, we tried to make it an adaptive design, so that the procedures you do with the human volunteer—blood draws, clinical assessments, and other evaluations—were standardized. In that sense, it was a little bit different than what I had done in the past, but it was a traditional study protocol that any PI could pick up and feel very comfortable with, because it had the same components as other study protocols they had seen in the past. My other duty, other than basically writing these documents and revising them, was answering calls, like we said before, talking to the PIs and

individuals at the site and making sure that their questions were answered in a timely manner, so that we could enroll individuals in a timely manner and follow them as best we could and in line with the protocol. Those were my major tasks and responsibilities.

Dempsey: I am a Program Officer in the Virology Branch, but I serve as sort of a clinical project manager on a lot of different trials that are part of my branch and under that purview. I served as the primary clinical project manager for this trial. I mean, we had a team of us that were required to manage this trial from an operational standpoint, but a lot of what I focused on was really getting the processes in place to get the drug to the sites, to get the sites open for enrollment, and to make sure that they had provided all the paperwork and all the documentation that was required to be able to legally allow them to administer the drug as part of the trial. We focused on operationalizing the Data and Safety Monitoring Board and getting what's called "charters" and all of those kinds of documents in place so that could be run smoothly. And just sort of operationalized a lot of the pieces of the trial.

Nayak: I suppose I had a little bit less of a clearly defined role. I contributed to the protocol writing with Kay, and some of the manuals of procedures and informed consent forms. I had oversight of several of the contracts that were used in the conduct of the trial—so oversight of budgets and then ensuring that we had funding and moving that funding all around. I oversaw all the Institutional Review Board applications and was just there for operational troubleshooting when issues came up.

Dodd: My role was a Study Statistician. I'm in the Biostatistics Research Branch, and we have a section called the Clinical Trials Research Section. We focus on clinical trials during outbreaks. My job on this trial was to listen to all the other investigators to make sure that information was translated into the relevant study endpoints and the right data collection tools. I also had to make sure those data collection elements were connected to analyses so that we could end up analyzing the data and make relevant conclusions about the study products. I spent a lot of time helping prepare and directing what the statistical analysis should be—setting up and directing the Data Safety Monitoring Board before they started, about what kinds of data they would be looking at and analyzing when they met. Then I had to step away from that, because they're independent—the DSMB's work is separate from the study team. Another role was working with my colleagues you are interviewing as well as the rest of the study team, to help write the final manuscripts when that time came.

Barr: Well, that's quite a lot for all of you. Have you all been involved in other COVID-19 research projects or initiatives beyond these ACTT trials and can you briefly introduce some of them?

Beigel: For many of us COVID has dominated our last two years. I mean, Seema and I have been involved with ACTT, the ACTIV-5, the Moderna phase one studies, some of the Moderna variant studies, mix and match vaccine studies, and now the new COVAIL [COVID-19 Variant Immunologic Landscape] trial. Seema has actually done more.

Nayak: Yeah, I was also involved in several of the major phase three COVID vaccine trials from Moderna, Novavax, Sanofi, and AstraZeneca, and also with the some of the pediatric vaccine trials.

Beigel: Kay, did you have others beyond ACTT?

Tomashek: No, I was just ACTT.

Beigel: It consumed Kay's life for that year and a half. Walla, anything else?

Dempsey: No, nothing else for COVID.

Nayak: Walla forgets that she is now being pulled into COVAIL.

Dempsey: Peripherally.

Barr: Can you describe more about that?

Nayak: This was, again, another fast-paced trial, and we needed experienced people that could get the job done. That's Walla in a nutshell.

Barr: That's high praise and very good that you have her. In addition to being scientists and medical professionals, you're also people who have been living through the pandemic. Briefly, can you all talk about some of your personal opportunities and challenges during COVID and how you've stayed grounded amid so much turmoil going on?

Nayak: I have two very small children. The country went into lockdown and suddenly I had no childcare, which is always an interesting challenge. At least it gave me a chance to see into my kid's school lives when we went to virtual school. They got to see my work life as well—I think all of my research teams have now met my kids, and my son can tell you what a double blind, randomized, placebo-controlled trial is, and he's seven, so I take that as a win.

Barr: Definitely.

Tomashek: My kids are a little older than Seema's children. In 2020, when all of this hit, my son was a senior in high school, and my daughter was a freshman in high school. The thing about having them at home—I mean, it was very difficult, right? It's his senior year in high school, and so he missed his prom and everything, but I think it did bring my children closer together, and it was really nice to have them home with us. We got a dog who is just adorable. We made the best of it, and I think we grew as a family. It was difficult, and it was especially difficult to be isolated from our extended family and not to be able to go visit our family members who don't live in the area. But I think we all—even the older people in my family—learned how to do Zoom calls. We made the best of it, and now that things have loosened up, we're able to go and visit them.

Barr: That's wonderful.

Dodd: I have three kids and my husband . He works at the Federal Reserve Board, so he was doing his part to help keep the economy running. I would get up at 5 or 6 in the morning, be working by 6 or 6:30, and then work all day. We would barely see each other for the first several months. Occasionally one of us would say, “Hey, did the kids get out of bed?” The kids, fortunately, were old enough. They were older than Seema’s kids, so they knew how to set their own alarms, and they were sort of forced to be more independent. I'm not saying we did it right by any means. I think there's a lot we got wrong, but everybody was forced to step up. We had to get each other's back in that regard. It was also good to be home more, because I couldn't travel anymore, and it was great. It was a great time to be together with the kids before they all go off to college.

Barr: Walla, do you have anything you want to share about highs and lows for you during the pandemic?

Dempsey: I guess the high was really the camaraderie—that everybody pulled together. There's no turf—there was nothing that impeded getting the job done. There were challenges, but nothing petty that was created, like disagreements or whatever. Friends, family—everybody was very supportive. My dog even loved having me home all the time, so that was good.

Beigel: There’s a certain reward that comes to working on diseases that touch this many people and knowing that you made an impact. We were all exhausted, but also energized by it. And you know, I think we were very lucky to have such a strong team that made all this happen. I was very lucky to have such a strong team.

Barr: That is wonderful. Well, I wish all of you continued success and continued health. Thank you very much for speaking with me about some of your experiences to date with COVID.

Beigel: Well, thanks for inviting us.

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